

A randomised trial to compare i-gel™ and ProSeal™ laryngeal mask airway for airway management in paediatric patients

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ABSTRACT

Background and Aims: i-gel™ is a newer supraglottic airway device with a unique non-inflatable cuff. We aimed to compare i-gel™ with ProSeal™ laryngeal mask airway (PLMA™) in children scheduled for surgery under general anaesthesia (GA) with controlled ventilation. **Methods:** This prospective, randomised controlled study was conducted in 100 surgical patients, aged 2–6 years of American Society of Anesthesiologists Physical Status I–II scheduled under GA. Patients were randomly allocated to receive either size 2 i-gel™ or PLMA™ as an airway device. The primary aim was oropharyngeal leak pressure assessed at 5 min following correct placement of the device. Secondary outcomes measured included number of attempts, ease of insertion, time of insertion, quality of initial airway, fibre-optic grading and effects on pulmonary mechanics. Statistical analysis was done using paired *t*-test and Chi-square test. **Results:** The demographic data were similar in both the groups. The oropharyngeal leak pressure in the i-gel™ group was 29.5 ± 2.5 cmH₂O as compared to 26.1 ± 3.8 cmH₂O in PLMA™ group ($P = 0.002$). The time taken for successful insertion in PLMA™ was longer as compared to i-gel (12.4 ± 2.7 vs. 10.2 ± 1.9 s, $P = 0.007$). The quality of initial airway was superior with i-gel™. The number of attempts, ease of insertion of supraglottic device, insertion of orogastric tube and pulmonary mechanics were similar in both the groups. **Conclusion:** Size 2 i-gel™ exhibited superior oropharyngeal leak pressure and quality of airway in paediatric patients with controlled ventilation as compared to PLMA™ although the pulmonary mechanics were similar.

Key words: Anaesthesia, i-gel, oropharyngeal leak pressure, paediatric patients

Access this article online

Website: www.ijaweb.org

DOI: 10.4103/0019-5049.191670

Quick response code



INTRODUCTION

Endotracheal intubation remains the gold standard for airway management in paediatric patients. However, at times, conventional laryngoscopy and intubation may not be possible and alternative techniques of airway management such as supraglottic airway devices (SADs) may be required. Both classic™ laryngeal mask airway (cLMA) and ProSeal™ laryngeal mask airway (PLMA) have been successfully used for securing a patent airway; however, due to high-cuff pressure-related complications, they can cause mucosal damage, sore throat, hoarseness and nerve palsies.^[1,2]

A second-generation SAD, i-gel™ (Intersurgical Ltd., Wokingham, Berkshire, UK) has been introduced

with unique features. The i-gel™ has thermoplastic elastomer gel with non-inflatable cuff and a channel for gastric suction catheter placement that precisely mirrors perilaryngeal anatomy, thereby no cuff inflation is required.^[3,4]

Studies are now focusing on SADs, which can provide ventilation with low peak airway pressure, higher

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How to cite this article: Nirupa R, Gombar S, Ahuja V, Sharma P. A randomised trial to compare i-gel and ProSeal™ laryngeal mask airway for airway management in paediatric patients. *Indian J Anaesth* 2016;60:726-31.

compliance, low resistance and high leak pressure so that they can provide wider margin of safety for ventilation. The primary aim of the present study was to compare oropharyngeal leak pressure of size 2 i-gel™ and PLMA™ for airway management in paediatric patients. The secondary outcomes measured were number of insertion attempts, insertion time, ease of insertion of size SGDs (2 i-gel™ or PLMA™) and orogastric catheter, quality of initial airway, fibre-optic grading and pulmonary mechanics.

METHODS

This prospective, randomised controlled study was conducted during April 2013–April 2014 after approval of the Institutional Ethics Committee (GMC/TA – I [19D]/2013/05428/22) and registration in the Clinical Trial Registry India (CTRI/2013/08/003898). After parental written informed consent, 100 children of American Society of Anesthesiologists Physical Status I and II of either sex, aged between 2 and 6 years, weighing between 10 and 30 kg, scheduled for elective surgeries of <1 h requiring general anaesthesia (GA) with controlled ventilation were enrolled. The exclusion criteria were patients with upper respiratory tract infection, anticipated difficult airway, non-fasting status and cardiorespiratory disease.

All patients were kept fasting for 4–6 h and premedicated with 0.3 mg/kg midazolam syrup 30 min before surgery. GA was induced with sevoflurane (inspired concentration 4–6%) with 50% nitrous oxide in oxygen, and then an intravenous (i.v.) access was established which was followed by fentanyl 2 µg/kg, i.v. After checking for mask ventilation, neuromuscular blockade was achieved with i.v. atracurium besylate 0.5 mg/kg. The patient's lungs were ventilated with a facemask for 3 min to allow for full relaxation of the jaw before placing the device. Patients were allocated just before device insertion to either size 2 PLMA™ or i-gel™ (50 patients each) based on sequentially computer-generated numbers concealed in opaque sealed envelopes. Anaesthesiologist not involved in the study generated the random number table. The anaesthesiologist inserting the device could not be blinded, but the assessor anaesthesiologist and patient were blinded to the group allocation. An opaque sheet was used to separate head-end from the monitor. The anaesthesiologist who inserted either of the two airway devices had performed at least 50 PLMA™ and 20 i-gel™ insertions.

Size 2 i-gel™ was inserted by firmly holding the device such that the cuff outlet was facing the chin of the patient, and it was then guided along the hard palate until definitive resistance was felt. The insertion of PLMA™ was performed as per the manufacturer's recommendation, using the introducer technique.^[5,6] The cuff of PLMA™ was inflated with 10 ml of air. A lubricated orogastric tube (OGT) was inserted through the drain tube after insertion of SGDs. Correct OGT placement was determined by suction of fluid or detection of injected air by listening with a stethoscope over the epigastrium. The PLMA™ or i-gel™ was then connected to the circle system of anaesthesia machine (Aestiva 5™ 7900, GE Healthcare, Datex-Ohmeda Division, Helsinki, Finland) using paediatric circle system. Manual ventilation was started after confirming the correct placement of SAD. Effective ventilation of the device was judged as a square wave capnograph trace and bilateral chest movements on gentle manual ventilation. In the event of partial or complete airway obstruction or a significant air leak, the device was removed and reinsertion was attempted. A maximum of three insertion attempts were allowed before the device was considered a failure. An alternative device, endotracheal tube was used in such a situation. The time interval between picking up the i-gel™ or PLMA™ and obtaining an effective airway was recorded as insertion time. The number of insertion attempts to effective ventilation was recorded. The ease of insertion was graded as very easy - if the device could be inserted without any manipulation, easy - if there was only one manipulation required and difficult - if any difficulty more than that. The quality of the initial airway was assessed during manual ventilation, with the pop-off valve set to limit peak airway pressure (PIP) to 20 cm H₂O. The initial airway was judged as follows: Excellent - no audible leak; good - an audible leak with relevant loss of air but sufficient ventilation, as indicated by an EtCO₂ <40 mm Hg and poor - clinically relevant loss of air and insufficient ventilation, requiring repositioning or replacement of the device.^[7] Air entry in the stomach and abnormal airway sounds over the larynx on auscultation were noted. After obtaining an effective airway, the oropharyngeal leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and the airway pressure (maximum allowed 40 cm H₂O) at which equilibrium reached was observed. Detection of an audible gas leakage at mouth and auscultation of gas leakage in the anterior neck was also performed in both

the groups. The patient's lungs were ventilated with a tidal volume of 5–7 mL/kg, and the respiratory rate was adjusted to maintain EtCO₂ of 35–40 mm Hg with inspiratory: expiratory ratio of 1:2. After successful insertion of the device, fibre-optic assessment of airway tube (Pentax Medical Singapore Pvt. Ltd., 438A Alexandra Road, Singapore) was obtained by passing fibroscope through the airway tube. The view was graded as 1 = vocal cords not seen; 2 = vocal cords and anterior epiglottis visible; 3 = vocal cords and posterior epiglottis visible; 4 = only vocal cords visible.^[6] Pulmonary mechanics including compliance, resistance, mean airway pressure, peak airway pressures as shown on anaesthesia workstation were recorded in both the groups at 2 min and 5 min after device insertion. We recorded any device failure, intraoperative displacement, gastric insufflation, regurgitation, laryngospasm, bronchospasm and airway obstruction. Data about fibre-optic position of the airway tube, ease of insertion of SGD, ease of OGT insertion, quality of initial airway, failed passage into the pharynx, malposition and the cause of failure were evaluated by the anaesthesiologist performing airway device insertion. The assessor anaesthesiologist collected data regarding oropharyngeal leak pressure, insertion time, ventilation and pulmonary mechanics. Secondary outcomes included number of attempts, ease of device and OGT insertion, fibre-optic view and pulmonary mechanics. After the completion of surgery, anaesthesia was discontinued and residual neuromuscular blockade was antagonised with neostigmine methyl sulphate 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. The SADs were removed once the patient was awake or could be easily aroused.

The sample size was calculated considering a projected difference of 30% between the two groups^[4] for airway leak pressures to be significant, at 95% confidence limits, a Type 1 error of 0.05 and a power of 80%. The data were analysed using International Business Machines Corporation SPSS Statistics for windows (version 22.0, Armonk, NY). Kolmogorov–Smirnov test was used for normality of distribution. Parametric data were compared using an unpaired *t*-test. Non-parametric data were compared with Fisher's exact test or Chi-square test. Data were presented as mean \pm standard deviation with $P < 0.05$ as statistically significant.

RESULTS

A total of 122 children were screened, 10 children were excluded due to upper respiratory tract infection

and in 12 children the parents refused to participate in the study. Therefore, we enrolled 100 paediatric patients. [Figure 1]. There were no differences in demographic characteristics of patients between the groups as shown in Table 1. The oropharyngeal leak pressure in i-gel™ group was 29.5 ± 2.5 (95% confidence interval [CI], 28–30) cmH₂O as compared to 26.1 ± 3.8 (95% CI, 24–27) cmH₂O in PLMA™ group ($P = 0.002$) [Table 2, Figure 2]. Insertion time was shorter for i-gel™ as compared to PLMA™ and none of the patients had failures in the insertion of SADs. The number of attempts, ease of insertion of SGDs and fibre-optic grading of airway tube were comparable as shown in Table 2. The quality of initial airway was better in i-gel™ as compared to PLMA™ ($P = 0.018$). Pulmonary mechanics including peak airway pressure, mean airway pressure, resistance and compliance were similar in both the groups as shown in Table 3. Success rates of OGT placement and fibre-optic grading were similar in both the groups. None of the patients experienced any adverse event including intraoperative displacement of SADs, gastric insufflation, regurgitation, laryngospasm, bronchospasm and airway obstruction in both the groups.

DISCUSSION

The study exclusively compared oropharyngeal leak pressure of size 2 i-gel™ with size 2 PLMA™ and pulmonary mechanics in paediatric patients under GA with controlled ventilation. We chose size 2 to bring uniformity in the use of two devices in children aged 2–6 years weighing 10–30 kg as the recommended weight range for the size 2 PLMA™ is 10–20 kg, whereas it is 10–25 kg for the i-gel™. The results of our study demonstrated higher leak pressure in size 2 i-gel™ as compared to size 2 PLMA™. This could be attributed first to the unique non-inflatable cuff of i-gel, which mirrors the perilaryngeal anatomy appropriately. Second, the leak pressure of i-gel appears to improve with time due to thermoplastic material, which forms a more efficient laryngeal seal after warming to body temperature.^[7] To obviate this effect, we measured the leak pressure after 5 min of correct placement of i-gel. Currently, some studies show higher leak pressure in i-gel™ as compared to PLMA™^[4,9,10] while others show similar leak pressure with both the devices.^[11,12] In a meta-analysis, i-gel™ was compared with several types of laryngeal mask airways (LMAs) in children and authors reported no evidence for differences in rate of insertion at first attempt, insertion time, ease

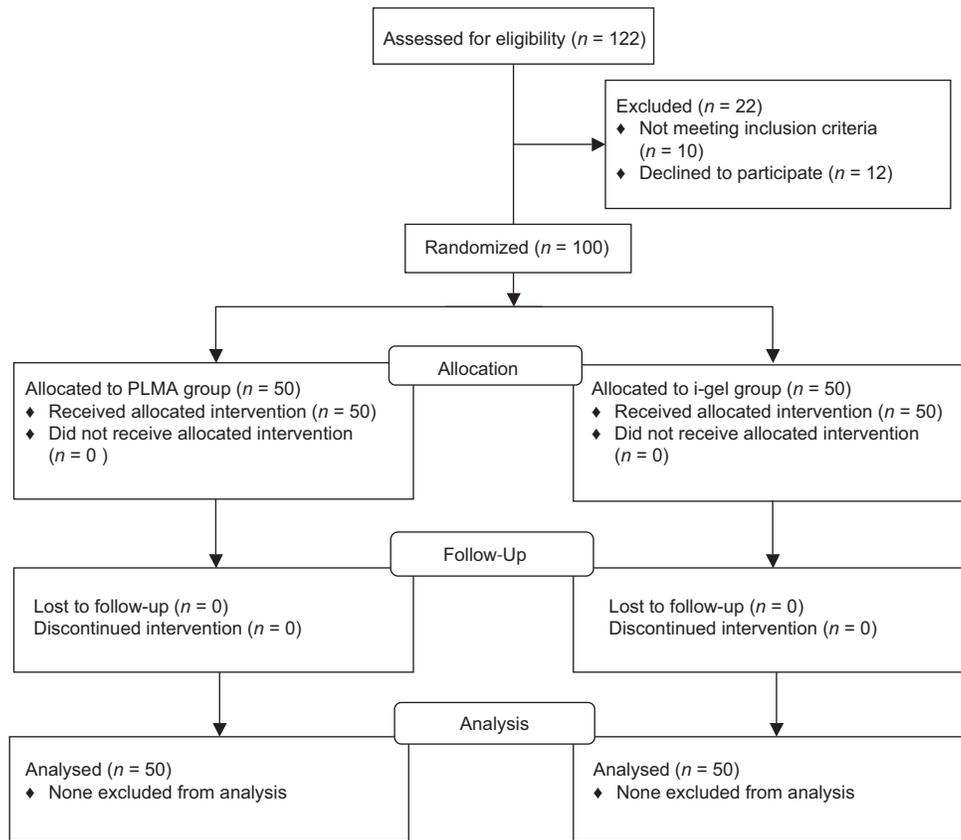


Figure 1: Consort flow chart

Demographics	PLMA™ (n=50)	i-gel™ (n=50)
Age (years)	3.9±1.4	4.1±1.4
Male/female, n (%)	24/26 (48/52)	24/26 (48/52)
Weight (kg)	15.3±4.6	16.7±4.9
Type of surgery, n (%)		
Ophthalmic	27 (54)	28 (56)
Orthopaedic	17 (34)	17 (34)
General surgery	6 (12)	5 (10)

Values are n (%) or mean±SD. PLMA-ProSeal™ laryngeal mask airway; SD—Standard deviation

Airway characteristics	PLMA™ (n=50)	i-gel™ (n=50)	P
Oropharyngeal leak pressure (cmH ₂ O)	26.1±3.8 (24-27)	29.5±2.5 (28-30)	0.002*
Number of insertion attempts (1/2/3)	46/4/0	50/0/0	0.31
Insertion time (s)	12.4±2.7	10.1±1.9	0.007*
Ease of insertion (very easy/easy/difficult) [†]	40/7/3	47/1/2	0.11
Quality of initial airway (excellent/good/poor)	26/19/0	37/13/0	0.018*
Fibre-optic grading (4/3/2/1) [‡]	36/10/4/0	36/12/1/1	0.37

Data are mean±SD (range) or n (%). *P<0.05 is considered statistically significant; [†]Ease of insertion; [‡]Fibreoptic score. PLMA-ProSeal™ laryngeal mask airway; SD-Standard deviation

of insertion or gastric tube insertion.^[13] The mean oropharyngeal leak pressure was 3.29 (2.25–4.34) cm H₂O higher with i-gel™ as compared to other LMAs.^[13] In an another meta-analysis, i-gel™ was found to be equally effective and provided a significantly higher leak pressure as compared with PLMA™ and cLMA.^[14] However, in these studies,^[13,14] authors used different sizes of SADs and none of these studies compared size 2 i-gel™ versus PLMA™ in paediatric patients undergoing surgery under GA with controlled ventilation.

In the present study, time taken for successful insertion of i-gel™ was less as compared to PLMA™ group. This difference was first due to the less flexible stem in i-gel™ as compared to PLMA™ and second due to the presence of prefilled elastomeric cuff in i-gel allowed to omit the step of inflating the cuff. This is in contrast with Saran *et al.*,^[12] who found comparable insertion times with both the devices. This might be attributable to different techniques of insertion of PLMA™ as Saran *et al.*^[12] used digital technique whereas in the present study an introducer technique was used. The insertion time for i-gel™ group in the present study was shorter as compared to previous studies.^[15,16]

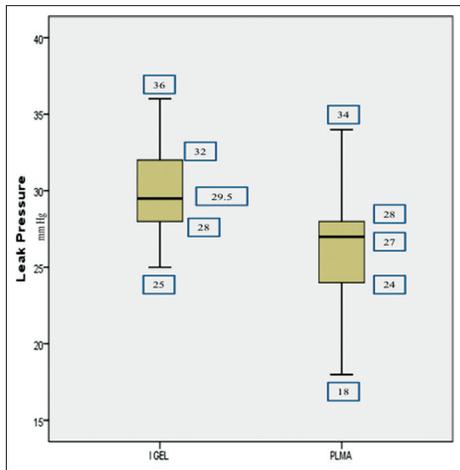


Figure 2: Oropharyngeal leak pressure of i-gel versus ProSeal™ laryngeal mask airway in paediatric patients undergoing general anaesthesia with controlled ventilation

Table 3: Airway parameters after placement of supraglottic airway device

Airway parameters	PLMA™ (n=50)	i-gel™ (n=50)	P
Peak airway pressure (cmH ₂ O) (min)			
2	12.92±2.10	13.36±2.46	0.33
5	13.16±2.46	13.88±2.67	0.16
Resistance (cmH ₂ O/L/s) (min)			
2	9.40±4.0	9.56±3.41	0.83
5	9.46±3.68	9.64±3.76	0.81
Compliance (L/cmH ₂ O) (min)			
2	22.3±6.16	22.04±6.29	0.39
5	22.5±6.00	23.56±6.35	0.77
Mean airway pressure (cmH ₂ O) (min)			
2	6.62±2.19	7.0±2.26	0.92
5	6.58±2.26	6.72±1.9	0.5

Data are mean±SD. PLMA–ProSeal™ laryngeal mask airway; SD–Standard deviation

Success rate, number of insertion attempts, ease of SGD and OGT insertion was found to be comparable in both the groups. The quality of initial airway in the present study was superior in i-gel™ as compared to PLMA™, which are similar to other studies.^[17] Our study showed similar fibre-optic grading in both the groups, which was consistent with other studies.^[11,12,14] The present study found similar pulmonary mechanics including resistance, compliance, peak airway pressure and mean airway pressure in both the groups. Saran *et al.* measured only peak airway pressure^[12] and so far no other study has measured pulmonary mechanics in detail. In the present study, there were no significant haemodynamic changes on comparing i-gel™ and PLMA™ and were accordance with published literature.^[4,18]

The present study found similar margin of safety for ventilation in i-gel™ as compared to PLMA™ in patients weighing between 10 and 30 kg receiving GA with positive pressure ventilation. The novelty of the study is firstly, higher oropharyngeal leak pressure in i-gel as compared to PLMA™ which ensures wider safety margin for ventilation in children 2–6 years weighing 10–30 kg and secondly, comparison of pulmonary mechanics in these children on controlled ventilation with size 2 i-gel™ or PLMA™, which has not been reported earlier in literature.

There were certain limitations of our study. First, the study involved patients with a normal airway and whether the same outcome can be extrapolated to patients with difficult airway is subject to performance of similar large-scale studies in patients with difficult airway. Second, the blinding was not possible for the anaesthesiologist inserting the device and fibre scope. Third, the airway device insertion was done under muscle relaxant effect, so the results are not necessarily the same for spontaneously breathing and less deeply anaesthetised patients. Fourth, our findings only apply to use of the size 2 devices in children aged 2–6 years weighing 10–30 kg.

CONCLUSION

Size 2 i-gel™ exhibited superior oropharyngeal leak pressure and quality of airway in paediatric patients with controlled ventilation as compared to same sized PLMA™ although the pulmonary mechanics were similar.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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